

REMARKS**Response to Arguments**

Claim 1 is amended to read "anesthesia" instead of "anesthetic." Support for this change is found in the specification at p. 2, lines 23-26.

Rejection Under 35 U.S.C. § 103

Claims 1-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Arnold (US 5,670,516) in view of Current Therapy (1977). Claims 1-5 are directed to a method of producing spinal anesthesia using 6-[2-(1(2)H-tetrazole-5-yl)ethyl]decahydroisoquinoline-3-carboxylic acid.

Arnold et al. teaches the use of 6-[2-(1(2)H-tetrazole-5-yl)ethyl]decahydroisoquinoline-3-carboxylic acid as an analgesic agent and to treat spinal cord trauma. Arnold does not teach the use of 6-[2-(1(2)H-tetrazole-5-yl)ethyl]decahydroisoquinoline-3-carboxylic acid for spinal anesthesia.

Analgesia is a decrease in pain. An analgesic drug decreases a patient's report of pain. Many drugs have analgesic properties. When injected into the spinal fluid, opioids (narcotics) produce analgesia. Clonidine also produces analgesia when injected into the spinal fluid around the spinal canal. These drugs, by themselves, do not produce anesthesia.

Anesthesia is the complete blockade of the motor and sensory response during surgery. That is, the patient can not perceive surgery is occurring and does not respond to the surgery with any movement.

Not all analgesic drugs are anesthetic drugs. Narcotic analgesic drugs can not by themselves produce anesthesia. Nonsteroidal anti-inflammatory drugs are analgesic but are not

anesthetics. In short, an analgesic drug is not the same as an anesthetic drug. The current claims (1-5) are narrowly focused on a method of spinal anesthesia.

The Applicant strongly disagrees with the notion that injection of an analgesic intrathecally (spinally) will obviously produce spinal anesthesia:

1. A local anesthetic is a sodium channel blocking drug that when administered locally produces local anesthesia, when injected on nerves produces regional anesthesia or when injected in the intrathecal space produces spinal anesthesia. Previous to this discovery, only local anesthetics could produce spinal anesthesia.
2. Drugs that produce anesthesia (volatile anesthetics) like isoflurane, desflurane, sevoflurane, and halothane cannot produce spinal anesthesia. Other drugs with anesthetic properties (intravenous anesthetics) like propofol, ketamine, sodium thiopental and pentobarbital do not produce spinal anesthesia when injected into the intrathecal space. Thus, many drugs have anesthetic properties; none produce spinal anesthesia.
3. Similarly, many drugs have analgesic properties (narcotics, nonsteroidal anti-inflammatory drugs, clonidine etc), none can produce spinal anesthesia.
4. 6-[2-(1(2)H-tetrazole-5-yl)ethyl]decahydroisoquinoline-3-carboxylic acid does not have any local anesthetic (sodium channel blocking) properties. It does not produce local anesthesia. Therefore, it is not obvious it will produce spinal anesthesia when injected intrathecally.
5. When injected intravenously, 6-[2-(1(2)H-tetrazole-5-yl)ethyl]decahydroisoquinoline-3-carboxylic acid produces analgesia. All other intravenously administered drugs with analgesic properties do not produce spinal anesthesia when administered intrathecally. 6-[2-(1(2)H-tetrazole-5-

yl)ethyl]decahydroisoquinoline-3-carboxylic acid produced spinal anesthesia. Therefore, its effect is not obvious.

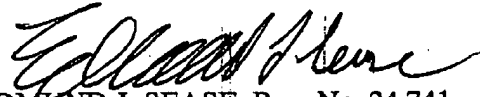
Arnold et al. teaches that 6-[2-(1(2)H-tetrazole-5-yl)ethyl]decahydroisoquinoline-3-carboxylic acid can treat spinal cord trauma (col. 35, line 46). However, the list of ways to administer the drug (col. 35, lines 30-34) does not include intrathecal administration. This is because treatment for spinal cord trauma is completely different than spinal anesthesia. In patients with spinal cord trauma, drugs like this can be administered intravenously to try to reduce the damage caused by the trauma. That damage caused by nervous system trauma results in fibrosis and nerve loss. Later long-term sensory and motor dysfunction occurs. Treatment of spinal cord trauma with this class of drugs attempts to prevent nerve loss secondary to injury. This is usually accomplished by injecting a drug into a vein immediately after trauma has occurred. For spinal anesthesia, the intrathecal injection delivers the drug to the fluid surrounding the spinal cord so that surgery can proceed. The method and purpose for using 6-[2-(1(2)H-tetrazole-5-yl)ethyl]decahydroisoquinoline-3-carboxylic acid are distinct between Arnold et al. and the present invention.

The phrase in claim 1, a "small but anesthesia producing amount of 6-[2-(1(2)H-tetrazole-5-yl)ethyl]decahydroisoquinoline-3-carboxylic acid" is not indefinite. "An effective amount" is indefinite only when the claim fails to state the function which is to be achieved. In re Frederiksen and Nielsen, 102 U.S.P.Q. 35, 36 (1954). Claim 1 states the function as anesthesia, therefore the claim language is acceptable.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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